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Feedback from Lif – The Swedish Association of the Pharmaceutical Industry

Stockholm 2021-04-27
To: European Commission

Revision of the EU general pharmaceuticals legislation

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Lif supports an agile, pragmatic and risk-based regulatory framework and a strong incentives' system that encourage advances in science, technology and medicines. However, EU legislation itself cannot solve issues around access and affordability, which are in close connection to national competences. We therefore believe that a solid analysis of the current regulatory framework and root causes of unavailability and access delays is important.

In carrying out the analysis of the existing regulatory framework, the interconnection of the pharmaceutical legislation with the ongoing proposals for the reinforced role of EMA, the creation of HERA, the ongoing implementation of the Medical Devices Regulation and the EU IP Action Plan must be taken into account. Lif believes that keeping the existing legal instruments and the well-established dual marketing authorisation system would be beneficial for legal certainty and regulatory efficiency. Non-legislative initiatives such as updates to existing policy and guidance documents must be considered as valid instruments to deliver on the objectives.

Lif would like to highlight the following considerations for developing the policy options:

- Reinforce expertise-driven assessment and enable a more agile centralised authorisation framework by removing unnecessary interfaces between EC, EMA & Committees.
- Enhance expedited pathways framework supporting innovation.
- Expand the role of EMA in the assessment of drug-device/diagnostic combination products.
- Replace the paper patient information leaflets with electronic versions. Improve the content of the leaflet reflecting patients' needs and adherence improvement.
- Modernise the current variations system to reflect evolution in technology and regulatory needs.
- Facilitate the change of legal status of medicines to ensure greater access and availability of non-prescription pharmaceuticals. Easing regulatory procedures for trusted molecules, which have been commercialised for many years and have a well-established safety profile, would help non-prescription medicines' availability for the benefit of the European citizens.

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- Enhance regulatory flexibility, proven useful during the COVID19 crisis, in a post-pandemic scenario to foster a smart regulation approach: specific measures which have been introduced could be considered for permanent establishment.
- Support environmental risk assessments to cover product lifecycle and address sustainability via initiatives encouraging prudent use of pharmaceuticals.
- Ensure proportionality of any measures aiming to prevent shortages to the level of risk of the product to be in short supply and not having therapeutic alternatives. Smart regulation can be a way forward to increase accessibility and availability of pharmaceuticals to patients. Consider using the data stored in the interoperable network of national repositories (Falsified Medicines Directive) to provide additional intelligence in monitoring shortages
- Ensure the acceptance of RWE in medicines evaluation both pre- and post-authorisation

For areas where there is a lack of a viable market (e.g. antimicrobials) and where the current framework has not yet covered all needs (e.g. OMP/Paediatrics), novel incentives adapted to the specific challenges of particular disease areas should be considered.

It is important that incentives are predictable and do not change late in the development process. Since market access is primarily dependent on national and healthcare system related factors as well as market dynamics and cannot be predicted early in development, linking incentives to access could jeopardise the objectives of incentivising and improving access to innovation in the EU. Lif supports a High-Level Forum on Access to Health Innovation to address access related issues.

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